H.R. 2339, the Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act of 2019
Rules Committee Print – Section by Section

Title I – Food and Drug Administration

Sec. 101 – Cigarette Graphic Health Warnings

This section requires the Food and Drug Administration (FDA) to finalize rulemaking to implement graphic health warnings for cigarette packages within 12 months.

The Family Smoking and Tobacco Control Act (Tobacco Control Act) required graphic health warnings to be added to cigarette packages and in cigarette advertisements. However, ongoing litigation has delayed finalizing this provision. Studies around the world have shown that graphic health warnings are an effective way to inform consumers about the health risks of smoking, as well as a mechanism to prevent children and other nonsmokers from beginning to smoke.

Sec. 102 – Advertising and sales parity for all deemed tobacco products

This section extends FDA's 2010 final rule on the sale, distribution, and use of cigarettes and smokeless tobacco to all deemed tobacco products, including e-cigarettes. This provision ensures manufacturers of newly deemed tobacco products are held to the same advertising and sales requirements currently applied to traditional cigarettes. This includes prohibiting the distribution of non-tobacco merchandise that bears a tobacco product brand name or logo; prohibiting brand sponsorship of athletic, music, or other concert events by tobacco product manufacturers; prohibiting offering free gifts in consideration of purchasing a tobacco product; and prohibiting advertising or labeling of tobacco products in nontraditional mediums without first notifying FDA. FDA is required to promulgate a final rule amending these regulations that will take effect two years after the date of enactment.

Sec. 103 – Reducing child and adolescent nicotine addiction

(a) Applicability to All Tobacco Products
This section codifies into the Federal Food, Drug, and Cosmetic Act (FFDCA) FDA's authority over all tobacco products, pursuant to the 2016 final deeming rule.

Pursuant to the Tobacco Control Act, cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco were immediately covered by FDA's tobacco product authorities upon enactment. However, all other tobacco products were deemed under FDA's authority by regulation. This provision codifies the final regulation to statutorily extend FDA's "tobacco product" authorities to all tobacco products in the FF DCA.

(b) Prohibiting Flavoring of Tobacco Products
This section prohibits all characterizing flavors of all tobacco products, including menthol and mint within one year. It also removes all flavored e-cigarettes from the market within 30

days. This provision includes a narrow pathway for the use of characterizing flavors in e-cigarettes should FDA determine that a flavor would significantly increase the likelihood of smoking cessation among current users and not increase the likelihood of initiation, including youth initiation.

This section also clarifies that no individual who purchases, possesses, or consumes a prohibited flavored tobacco product, including a tobacco product that contains menthol, shall be subject to criminal penalties under the Act for such purchase, possession, or consumption, nor shall it be used as justification to stop, search, or conduct any other investigative measure against any individual.

Sec. 104 – Prohibition against remote retail sales

This section directs FDA to issue final regulations that prohibit non-face-to-face sales of certain tobacco products, including e-cigarettes and e-cigarette accessories. Given the lack of sufficient protections to prevent youth access to tobacco products online and the inability to ensure the same level of face-to-face identification and age verification with remote sales, this provision is intended to enhance protections against underage youth sales.

Sec. 105 – Fees applicable to all tobacco products

This section provides FDA with explicit authority to collect user fees from all classes of tobacco products, including newly deemed products such as e-cigarettes. It also increases the total amount of fees collected by $100 million, and future annual fees would be indexed to inflation. FDA would be required to submit annual performance and financial reports to Congress regarding the use of such user fees.

Sec. 106 – Regulation of products containing synthetic nicotine

This section directs FDA to issue an interim final rule within one year and a final rule within two years on the regulation of products containing synthetic nicotine or nicotine that is not made or derived from tobacco.

Sec. 107 – Update to youth tobacco prevention public awareness campaigns

The section directs the Secretary of Health and Human Services to update youth tobacco prevention public awareness campaigns and to modify materials to include individuals who are 18 to 21 years of age.

Sec. 108 – Exemption from premarket approval of certain tobacco products

This section exempts certain cigars from the prohibition of remote sales, requires FDA establish age verification procedures for remote sales of such certain cigars, and exempts such certain cigars from premarket review by FDA until September 30, 2028. Section 108 also clarifies that the Secretary shall withdraw the exemption if the Secretary determines that the cigar products resulted in an emerging public health threat or identifies a rise in the use of these products. The section also requires the National Academies of Sciences, Engineering, and Medicine to conduct a study on the public health impact of this exemption

and the youth usage and market share of these products.

Sec. 109 – Public education

Section 109 directs FDA to provide educational materials for health care providers, members of the public, and law enforcement officials regarding the authority of FDA with respect to the enforcement of regulations of tobacco products, including the prohibition on characterizing flavors and the public health impact of tobacco products with characterizing flavors.

Sec. 110 – Regulations for recordkeeping concerning tracking and tracing

Section 110 requires FDA to publish proposed and final rules regarding the recordkeeping requirements for tracking and tracing tobacco products. Section 110 requires these regulations to be finalized no later than two years after the date of enactment of H.R. 2339. The requirement that FDA issue regulations concerning the tracking and tracing of tobacco products, which would establish a system to follow tobacco products from the manufacturer to a retail setting, was enacted as part of the Tobacco Control Act. This requirement was intended to help assist in the investigation of illicit trade and diversion, as well as to ensure the integrity of the supply chain, however, FDA has yet to issue the required regulations.

Title II – Federal Trade Commission

Sec. 201 – Advertising of tobacco products

(a) Advertising of Electronic Nicotine Delivery Systems
This section makes it unlawful to market, advertise, or promote any e-cigarette products to individuals under the age of 21 or to market, advertise, promote, or endorse any e-cigarette product without clearly disclosing that the communication is an advertisement. This section would give the Federal Trade Commission (FTC) the authority to issue rules under notice-and-comment rulemaking to implement these prohibitions. It would also allow FTC to seek civil penalties for violations of statute, and it would allow state authorities to enforce the law.

(b) Report to Congress on Tobacco Product Advertising
This section requires FTC to issue a report to Congress within two years, and annually thereafter, on the domestic sales, advertising, and promotional activity of cigarette, cigar, smokeless tobacco, and e-cigarette manufacturers.

Title III – Public Health Programs

Sec. 301 – Outreach to medically underserved communities

Section 301 provides funding for community health worker grants to educate and provide guidance to medically underserved communities, particularly within ethnic and racial minority populations, regarding effective evidence-based strategies for tobacco, e-cigarette, and nicotine addiction cessation and prevention, including cessation of menthol flavored

tobacco products and e-cigarettes.

Sec. 302 – Demonstration grant program to develop strategies for smoking cessation in medically underserved communities

Section 302 directs the Centers for Disease Control and Prevention (CDC) to establish a demonstration program to award grants to state, local, tribal, or territorial public health departments to support the development of improved evidence-based strategies for smoking cessation in medically underserved communities, particularly racial and ethnic minority populations.

Sec. 303 – Public Awareness, Education, and Prevention Campaign

Section 303 directs CDC, in consultation with the Surgeon General, to develop and implement a national campaign to educate youth, young adults, parents, clinicians, health professionals, and others about the harms associated with the use by youth and young adults of tobacco products, including e-cigarettes.

Sec. 304 – Tobacco Cessation Treatment Grants to Health Centers

Section 304 provides funding to provide comprehensive tobacco cessation treatment, including counseling and tobacco cessation therapies in Community Health Centers.

Sec. 305 – Grants for Research

Section 305 invests in research to develop and improve effective strategies for cessation of the use of tobacco products, including cessation of flavored combustible cigarettes, including menthol-flavored cigarettes, cessation of e-cigarettes, and cessation and prevention strategies targeted toward youth. Research funds would also be provided to aid in the development of safe and effective tobacco cessation therapies, including therapies appropriate for populations under the age of 18.

Title IV – Nicotine or vaping access protection and enforcement

Sec. 401 – Increasing civil penalties applicable to certain violations or restrictions on sale and distribution of tobacco products

Section 401 increases the civil penalties applicable for certain violations of restrictions on sale and distribution of tobacco products, such as retailer violations related to underage sales.

Sec. 402 – Study and report on e-cigarettes

Section 402 requires the Comptroller General of the United States to study and issue a report to Congress not later than five years after the date of enactment of H.R. 2339 on the

relationship between e-cigarettes and tobacco cessation; the perception of the harmful effects of e-cigarettes; and the effects of secondhand exposure to smoke from e-cigarettes.

Title V – Internal Revenue Service

Section 501- Taxation of Nicotine

Section 501 establishes an excise tax on nicotine manufactured in or imported into the United States. The tax is $27.81 per gram of nicotine, which provides rough parity with the excise tax on cigarettes. This tax applies to nicotine not subject to existing federal excise taxes on tobacco products. The tax does not apply to FDA-approved nicotine replacement therapies.

Title VI – Further Health Investments

Sec. 601 – Waiving Medicare Coinsurance for Colorectal Cancer Screening Tests

Section 601 waives Medicare's coinsurance requirements for colorectal cancer screening tests regardless of whether such screening test resulted in the removal of a polyp.

Sec. 602 – Below the Deductible Coverage of Inhalers and Nebulizers for HSA-eligible High Deductible Health Plans

Sec. 602 allows high deductible health plans to offer inhalers and nebulizer for treatment of chronic lung disease below the deductible while remaining health savings account eligible.